

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., et al., Defendants.</p>	<p>Civil Action No. 04-2355 (JLL) OPINION</p>
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LINARES, District Judge.

This matter comes before the Court by way of Defendant Sun's motion for partial summary judgment seeking a ruling that Plaintiffs are not entitled to lost profits against Sun for lost Protonix sales [Docket Entry No. 1142]. The Court has considered the submissions made in support of and in opposition to the instant motion. No oral argument was heard. Fed. R. Civ. P. 78. Based on the reasons that follow, Defendant's motion is **denied**.

BACKGROUND

1. *General*

This is a patent infringement action to enforce United States Patent No. 4,758,579 ("the '579 patent"). The asserted claims of the '579 patent – claims 22 and 25 – cover a chemical compound named Pantoprazole, and its sodium salt, pantoprazole sodium. Pantoprazole is the active ingredient in PROTONIX®, a drug manufactured for the treatment of gastric acid

disorders (hereinafter referred to as “Protonix”). Plaintiff Nycomed GmbH (formerly known as Altana Pharma AG and, at the time of the invention, Byk Gulden) owns the ‘579 patent. Plaintiff Wyeth (formerly known as American Home Products Corporation) markets and sells Protonix in the United States as Nycomed’s exclusive licensee.

Protonix was approved by the FDA on February 2, 2000 and was first marketed to the public in 2000. Defendants Teva, Sun and KUDCo each filed an Abbreviated New Drug Application (“ANDA”) pursuant to the Hatch-Waxman Act, seeking FDA approval to sell a generic version of Protonix prior to the expiration of the ‘579 patent.

In May of 2004, Plaintiffs responded by suing Teva, Sun and KUDCo for infringement of the ‘579 patent. In addition to seeking equitable relief, Plaintiffs seek lost profits damages and/or reasonable royalty damages pursuant to 35 U.S.C. §284.

Plaintiffs’ motion for a preliminary injunction was denied in September 2007. Defendants Teva and Sun subsequently launched generic pantoprazole products “at risk,” i.e., before entry of final judgment on the merits of this litigation, and before the patent expired. Sun, Teva and KUDCo each stipulated to infringement of claims 22 and 25 of the ‘579 patent *if* those claims were ultimately found to be valid and enforceable.

A jury trial was conducted for several weeks in April 2010 with respect to Defendant Teva and Defendant Sun’s affirmative defenses and counterclaims that claims 22 and 25 of the ‘579 patent are invalid for obviousness and obviousness-type double patenting. Simultaneously, a non-jury trial was conducted with respect to Defendant KUDCo’s affirmative defenses and counterclaims. The jury returned a verdict in favor of Plaintiffs as to each issue tried. On July 15, 2010, the Court issued a bench opinion as to Defendant KUDCo. The Court ruled that KUDCo had not demonstrated by clear and convincing evidence that the asserted claims of the

‘579 patent are invalid either for obviousness under 35 U.S.C. § 103 or under the judicially created doctrine of obviousness-type double patenting. The parties subsequently began discovery on the remaining issues in the case—damages and Defendants’ claims of unenforceability.

The ‘579 patent expired on July 19, 2010. The FDA awarded Wyeth a period of pediatric exclusivity that expired on January 19, 2011.

2. *Sun’s Motion*

Defendant Sun now moves for partial summary judgment seeking a ruling that Plaintiffs are not entitled to lost profits against Sun for lost Protonix sales. In particular, Sun claims that Plaintiffs cannot establish the element of “but for” causation necessary to support their claim for lost profits against Sun because Plaintiffs’ lost profits theory improperly allocates *all* lost sales to the more expensive Protonix product and fails to take into account the existence of Wyeth’s cheaper generic product, which entered the market prior to the launch of Sun’s generic. According to Sun, the Federal Circuit’s decisions in *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538 (Fed. Cir. 1995), and *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995), *require*, as a matter of law, that Wyeth’s generic product be considered when conducting a lost sales analysis in this case. Thus, Sun maintains that Plaintiffs’ failure to include Wyeth’s generic in its lost sales analysis renders its “fictional January 30, 2008 world” entirely invalid.

Plaintiffs oppose Sun’s motion on the basis that Plaintiffs’ lost profits theory is based on a proper economic reconstruction of the market that existed prior to *any* infringement. In particular, Plaintiffs maintain that (a) Sun began infringing long before Wyeth launched its generic product, and (b) Wyeth launched its generic in response to and to mitigate the effects of

Sun's infringement; therefore, the appropriate "but for" infringement market excludes Wyeth's generic. In any event, according to the Plaintiffs, the quantum of damages and causation, including the reconstruction of the market "but for" infringement, are disputed material facts to be resolved by the jury.

A. *Facts Relevant to Sun's Motion*

Plaintiff Nycomed owns the '579 patent. (SUMF, ¶ 12; RSUMF, ¶ 12).¹ In or around 1997, predecessors of Nycomed and Plaintiff Wyeth entered into a License Agreement wherein Nycomed granted Wyeth an exclusive license to market and sell pantoprazole in the United States. (SUMF, ¶ 13; RSUMF, ¶ 13). *See generally* October 11, 2012 Opinion, Docket Entry No. 1209. Consistent with this agreement, Wyeth filed a New Drug Application with the FDA, seeking authorization to market Protonix in the United States. The FDA approved Wyeth's application on February 2, 2000 and Wyeth began selling Protonix in the United States that year. (SUMF, ¶¶ 14, 15; RSUMF, ¶¶ 14, 15).

On April 6, 2004, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") filed an Abbreviated New Drug Application (ANDA) with the FDA seeking to market a generic version of Protonix prior to the expiration of Nycomed's patent. Thereafter, on or about March 1, 2005, Defendant Sun Pharmaceutical Industries, Ltd. ("Sun") filed its own ANDA, which likewise sought the FDA's approval to sell a generic version of Protonix prior to the expiration of Nycomed's patent. (SUMF, ¶ 16; RSUMF, ¶ 16). In response to the ANDAs, Plaintiffs filed

¹ "SUMF" refers to Sun's Statement of Undisputed Material Facts. "RSUMF" refers to Plaintiffs' Response to Sun's Statement of Undisputed Material Facts.

separate lawsuits against Teva on May 20, 2004 and Sun on April 13, 2005, claiming infringement of the ‘579 patent in both actions. (SUMF, ¶ 17; RSUMF, ¶ 17).

Teva received FDA approval of its ANDA on August 2, 2007. Sun received FDA approval on September 11, 2007. (SUMF, ¶ 19; RSUMF, ¶ 19). Sun first shipped its ANDA product to the United States on or around December 18, 2007. (SAF, ¶ 34; RSAF, ¶ 34)² (Ruiz Decl., Ex. 71 at 7, Sun’s Response to Interrogatory No. 6); (SUMF, ¶ 23; RSUMF, ¶ 23).

At the beginning of December 2007, Wyeth was the only company selling a pantoprazole product in the United States. (SUMF, ¶ 20; RSUMF, ¶ 20). Teva launched its generic pantoprazole product on December 21, 2007. (SUMF, ¶ 22; RSUMF, ¶ 22). Sun launched its generic product on January 30, 2008. (SUMF, ¶ 37; RSUMF, ¶ 37) (RSAF, ¶ 57) (Ruiz Decl., Ex. 63, Vellturo Report, ¶ 7).

On January 29, 2008—the day before the official launch of Sun’s generic product—Wyeth authorized Prasco to launch Wyeth’s own generic version of Protonix—Wyeth OG (hereinafter referred to as “Wyeth’s generic”). (SUMF, ¶ 28; RSUMF, ¶ 28); (SAF, ¶¶ 46, 47; RSAF, ¶¶ 46, 47). Wyeth’s generic and branded Protonix are the same product. (SUMF, ¶ 33; RSUMF, ¶ 33). Sun’s generic competed with both Teva’s generic and Wyeth’s generic for generic pantoprazole sales. (SUMF, ¶ 50; RSUMF, ¶ 50).

The parties dispute whether actions by Teva and/or Sun had any impact on Plaintiffs’ decision to launch its own generic product. (SUMF, ¶¶ 24, 25; RSUMF, ¶¶ 24, 25). According to Sun, Wyeth launched its authorized generic to compete with Teva’s generic pantoprazole and Sun’s generic, in the event it was launched. (SUMF, ¶ 29). Sun further maintains that this

² “SAF” refers to Plaintiffs’ Statement of Additional Material Facts. “RSAF” refers to Sun’s Response to Plaintiffs’ Statement of Additional Facts.

decision was made by Wyeth regardless of whether Teva or Sun were supplying additional—or any, in the case of Sun—generic pantoprazole to pharmaceutical clients. (SUMF, ¶ 24). Plaintiffs, on the other hand, maintain that Wyeth launched its own generic in response to—and to mitigate damages caused by—Teva’s launch and Sun’s anticipated launch. (RSUMF, ¶ 29); (SAF, ¶ 45).

Once Teva and Sun launched their respective generic products, Plaintiffs amended their complaint to include claims for actual infringement. (SUMF, ¶ 38; RSUMF, ¶ 38). Thereafter, issues for trial were bifurcated, and the issue of patent validity was tried before a jury, which returned verdicts in the Plaintiffs’ favor. (SUMF, ¶ 39; RSUMF, ¶ 39). Plaintiffs now seek, *inter alia*, lost profits based on lost sales that were made by Sun’s generic pantoprazole. (SUMF, ¶ 41; RSUMF, ¶ 41).

On January 13, 2012, Wyeth’s principal damage expert, Dr. Christopher Velluro, provided an opinion—relied upon by Plaintiffs to establish the quantum of lost profit damage—that Sun’s generic diverted sales from Wyeth that would have been made with Protonix. (SUMF, ¶ 43; RSUMF, ¶ 43). Dr. Velluro used a hypothetical negotiation date of December 2007 for both Sun and Teva. (SUMF, ¶ 44; RSUMF, ¶ 44). Dr. Velluro’s analysis does not start from a reference point of the market that existed on January 30, 2008, but rather a market that would have existed had neither Teva nor Sun infringed. (SUMF, ¶ 46; RSUMF, ¶ 46) (Miller Decl., Ex. X, Velluro Dep. Tr. (May 30, 2012) at 474:14-21).

LEGAL STANDARD

Summary judgment is appropriate when, drawing all reasonable inferences in the non-movant’s favor, there exists no “genuine dispute as to any material fact” and the movant is

entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1273 (Fed. Cir. 2010).

The moving party is entitled to judgment as a matter of law when the non-moving party fails to make “a sufficient showing on an essential element of her case with respect to which she has the burden of proof.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). However, if a reasonable juror could return a verdict for the non-moving party regarding material disputed factual issues, summary judgment is not appropriate. *See Anderson*, 477 U.S. at 242-243 (“At the summary judgment stage, the trial judge’s function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.”). With this framework in mind, the Court turns now to Sun’s motion.

DISCUSSION

As previously stated, Sun moves for partial summary judgment seeking a ruling that Plaintiffs’ claim for lost profits damages fails, as a matter of law, because Plaintiffs cannot establish the necessary element of “but for” causation. In particular, Sun maintains that Plaintiffs’ failure to take into account the existence of Wyeth’s generic, which entered the relevant market prior to the launch of Sun’s generic, renders its entire theory of lost profits damages invalid. Based on the reasons that follow, the Court finds that there are genuine issues of material fact that preclude entry of summary judgment.

1. *Relevant Law*

Damages in patent infringement cases are governed by 35 U.S.C. § 284, which provides:

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

35 U.S.C. § 284. “Thus, the language of the statute is expansive rather than limiting. It affirmatively states that damages must be adequate, while providing only a lower limit and no other limitation.” *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995). The United States Supreme Court has clarified that, in enacting § 284, “Congress sought to ensure that the patent owner would in fact receive full compensation for ‘any damages’ he suffered as a result of the infringement.” *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654-655 (1983).

Generally speaking, the availability of lost profits is a question of law. *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1365 (Fed. Cir. 2008). However, “the correct measure of damages is a highly case-specific and fact-specific analysis.” *Id.* at 1366; *see generally Rite-Hite*, 56 F.3d at 1546 (“[T]he question of legal compensability is one ‘to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent.’ ”).

To recover lost profits damages, “the patentee must show a reasonable probability that, ‘but for’ the infringement, it would have made the sales that were made by the infringer.” *Rite-Hite*, 56 F.3d at 1545.³ In other words, the question to be asked in determining damages is “had the Infringer not infringed, what would the Patentee Holder-Licensee have made?” *Id.* (citation omitted). The “but for” inquiry “requires a reconstruction of the market, as it would have developed absent the infringing product,” in order to determine what the patentee would have

³ *See generally Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F.3d 1336, 1354 (Fed. Cir. 2001) (“Thus, a patentee may obtain lost profit damages for that portion of the infringer’s sales for which the patentee can demonstrate ‘but for’ causation and reasonable royalties for any remaining infringing.”).

made. *Grain Processing Corp. v. Am. Maize-Pros. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999); but see *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989) (“But ‘[t]he patent holder does not need to negate all possibilities that a purchaser might have bought a different product or might have foregone the purchase altogether.’ ”).

One way to establish “but for” causation is to meet the four-part test pronounced in *Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152, 1156 (6th Cir. 1978). *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1551 (Fed. Cir. 1994). To recover under the *Panduit* test, the patent owner must prove:

- (1) a demand for the patented product,
- (2) an absence of acceptable noninfringing substitutes,
- (3) manufacturing and marketing capability to exploit the demand, and
- (4) the amount of profit the patent owner would have made.

Id. However, “*Panduit* is not the *sine qua non* for proving ‘but for’ causation. If there are other ways to show that the infringement in fact caused the patentee’s lost profits, there is no reason why another test should not be acceptable.” *Rite-Hite*, 56 F.3d at 1548. In this regard, the Federal Circuit has made clear that “other fact situations may require different means of evaluation, and failure to meet the *Panduit* test does not *ipso facto* disqualify a loss from being compensable.” *Id.* (“If there are other ways to show that the infringement in fact caused the patentee’s lost profits, there is no reason why another test should not be acceptable.”). Thus, so long as a particular injury was or should have been “reasonably foreseeable by an infringing competitor in the relevant market, broadly defined, that injury is generally compensable absent a persuasive reason to the contrary.” *Id.* at 1546.

Ultimately, it is the patent owner’s burden to prove that “it actually lost sales or that at least such inference is reasonable from all of the evidence. That is the essence of a lost profits damage award.” *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 926 F.2d 1161,

1166 (Fed. Cir. 1991). But if the amount of the damages “cannot be ascertained with precision, any doubts regarding the amount must be resolved against the infringer.” *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983).

2. Analysis

The crux of the parties’ dispute lies in their divergent projections of the market as it would have developed absent infringement. More specifically, the parties dispute *when* the first act of infringement took place and, therefore, what products would have comprised the appropriate “but for” market. *See generally Grain Processing*, 185 F.3d at 1350 (noting that the “but for” inquiry requires a reconstruction of the market as it would have developed absent the infringing product).

According to Plaintiffs, Sun’s first act of infringement took place on December 18, 2007 (when it shipped pantoprazole into the United States), which was prior to the launch of either Teva’s generic *or* Wyeth’s generic. According to Plaintiffs, “the tablets Sun imported and sold to Caraco were eventually sold into the market, causing the very harm for which Plaintiffs seek lost profits.” (Pl. Opp’n Br. at 2). Thus, Plaintiffs’ theory of lost profits damages is based upon a hypothetical reconstruction of the market as it existed prior to December 18, 2007—before *any* infringement by Sun. Under this theory, any sales lost to Sun’s infringing product would have been made by Protonix, not Wyeth’s generic, which was not on the market as of December 2007 and is therefore irrelevant to any lost sales analysis.⁴ Plaintiffs have purposefully excluded

⁴ It should be noted that Plaintiffs do not seek lost profits on lost sales of Wyeth’s generic. *See* Vellturo Report, Ruiz Decl., Ex. 63, ¶ 133 (“I find that Plaintiffs suffered damages in the form of lost profits on lost sales of Protonix.”); ¶ 149 (“This is most starkly evident in the statistical analyses performed above that demonstrate Teva’s and Sun’s sales displaced expected sales of

Wyeth's generic from their hypothetical market based on the theory that Wyeth only launched its own generic in response to and to mitigate the effects of the launch of Teva's generic and the anticipated launch of Sun's generic; thus, Plaintiffs' theorize that absent Sun and Teva's infringement, Wyeth's generic would never have been on the market.

Sun, on the other hand, maintains that its first act of infringement took place on January 30, 2008—the date on which it officially launched its generic product. According to Sun, Plaintiffs' failure to take into account Wyeth's generic product—which entered the market the day before, on January 29, 2008—renders its entire hypothetical reconstruction of the market invalid, which, in turn, prevents Plaintiffs from establishing the requisite element of “but for” causation. To be clear, Sun does not argue (in this motion) that Wyeth's generic constituted a noninfringing substitute for purposes of the *Panduit* test. *See Reply Br. at 5.*⁵ Rather, Sun argues that Wyeth's generic was simply a substitute product that was available at the time of Sun's first infringing sale (January 30, 2008) and, therefore, should have been considered in any lost sales analysis. *See id.*

The Court begins its analysis by reiterating that the question of legal compensability is one “to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent.” *Rite-Hite*, 56 F.3d at 1546. This statement is particularly applicable in this case where the crux of the parties’ dispute relates to the existence and implications of a product that—according to the Plaintiffs—would never have existed absent the infringement at issue in this case.

Protonix, one-for-one In the ‘but for’ world, therefore, physicians and patients seeking pantoprazole would have turned to Protonix.”).

⁵ *See generally Rite-Hite*, 56 F.3d at 1548.

A. Evidence

In support of its position, Sun relies on, *inter alia*, an internal Wyeth document, dated January 28, 2008, recommending the immediate launch of Wyeth's generic and providing, in pertinent part, that (a) "based on all of the information we have gathered, it is our conclusion that in the very near future, Teva and Sun will flood the marketplace with hundreds of millions of additional generic tablets, in addition to the 300 million tablets (5 month supply) already in the marketplace," and (b) "even if Teva and Sun were not to put additional generic product into the market at this time, the impact of the current generic supply will be severe and the brand will not recover. . . . Protonix will lose its place on some formularies and be put in unattractive tiers on others." (Miller Decl., Ex. N at W01326593-95). In addition, Sun cites to an internal Prasco document, dated January 24, 2008, which states that "Customer commits their business for a 12-month period to Prasco in exchange for guaranteed sale for the next months at market competitive pricing regardless if Sun/Teva/Kudco are on the market." (Miller Decl., Ex. R, PR01340032). Finally, Sun refers to paragraph 118 of the expert report submitted by Plaintiffs' expert, Dr. Velluro, providing that "[f]acing these prospects, Wyeth implemented the most economically rational strategy available in the face of the actual at-risk launch of Teva in 2007 and the impending anticipated launch by Sun: the launch of the Wyeth OG." (Miller Decl., Ex. C, ¶ 118).

In opposition to Sun's motion, Plaintiffs have come forward with evidence to support their claim that Wyeth's generic was only launched in response to and to mitigate the effects of Sun's anticipated launch. For instance, Plaintiffs rely on a different section of the same internal Wyeth memo discussed above, dated January 28, 2008, which states, in pertinent part, "[w]e have also learned that Sun has taken substantial orders from all customer segments. These

reports come from multiple sources including Prasco, our Account Management team, and Kiran Mull. In addition, Sun told Wyeth that it is ready to ship product at risk. We believe based on information learned during discussions with Sun that it is prepared to ship at least 150 million tablets at this time.” (Ruiz Decl., Ex. 68, W01326593). Plaintiffs also cite an email from Neil Mahoney to Kiran Mull of Wyeth, dated December 17, 2007, stating: “All of Wyeth is closed from December 23, 2007 to January 1, 2008. We feel we need coverage for Protonix during that time period as rumors are flying on Teva. Sun thinks same and is gearing-up for that with their own finished product inventory. Can you confirm and keep your people vigilant.” (Ruiz Decl., Ex. 149). *See also* Panto Generic Letter Agreement, Ruiz Decl., Ex. 67 (W05598917) (“Sun has indicated its intent to launch its generic pantoprazole product also ‘at risk’ in the Territory. In light of these developments, the Parties acknowledge that in response to the actions of Teva and/or Sun, and given the resulting damage to the Protonix product, it is commercially desirable that Wyeth and Nycomed be able to launch their own generic pantoprazole product.”).

It is clear, based on the evidence submitted, that there are genuine issues of fact in dispute surrounding the issue of whether actions by Sun—beginning as early as December 2007—had any effect on Wyeth’s decision to launch its own generic. Moreover, the Court has already found that there is a genuine dispute of material fact as to whether Sun’s pre-launch activities—including the importation of its infringing generic product on or about December 18, 2007—caused financial loss to Plaintiffs. *See* December 20, 2012 Opinion at 13, Docket Entry No. 1231. As stated in this Court’s December 20, 2012 Opinion:

In support of its price erosion claim as to Sun’s pre-launch (i.e., pre-January 30, 2008) activities, Plaintiffs have come forward with, among other things, the following pieces of evidence: (1) an email chain stating that certain pallets of pantoprazole were shipped by Sun to Caraco (in Chicago) with an expected arrival

date as early as December 21, 2007,⁶ (2) Sun’s stipulation, in the context of this action, that its “importing into the United States of generic pantoprazole sodium tablets infringes claims 22 and 25 of U.S. Patent No. 4,758,579, if those claims are valid and enforceable,”⁷ (3) Dr. Vellturo’s testimony that “Teva and Sun’s infringement drove down the prices of pantoprazole below levels that would have been obtained ‘but for’ infringement”⁸ and (4) Dr. Vellturo price erosion calculation as it relates to Sun, which is not limited by the January 30, 2008 date.⁹ When viewed in the light most favorable to Plaintiffs, this evidence, if believed by a reasonable jury, could support a claim for price erosion damages as to Sun accruing prior to January 30, 2008.

Thus, the Court finds there to be a genuine dispute of material fact as to whether Sun’s pre-launch activities—including the importation of its infringing generic product—caused financial loss to Plaintiffs.

(*Id.* at 12-13). Although the Court’s ruling in this regard pertained to price erosion damages, and not lost profits damages in the form of lost sales, both categories of damages fall under the lost profits umbrella and cannot—based on the current record and for purposes of this motion—be considered in isolation from one another. *See, e.g., Hebert v. Lisle Corp.*, 99 F.3d 1109, 1119 (Fed. Cir. 1996) (“[D]amages may include lost profits due to diverted sales, price erosion, and increased expenditures caused by the infringement.”); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983) (“Lost profits may be in the form of diverted sales, eroded prices, or increased expenses.”); *see generally Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359,

⁶ (Ruiz Decl., Ex. 45) (SUN0064106) (“Please verify with the airlines and confirm that 12 pallets have actually been airlifted from Paris and arriving [in] Chicago tonight [December 21, 2007] at 11:30 P.M.”); (SAF, ¶ 34; RSAF, ¶ 34) (Ruiz Decl., Ex. 71 at 7, Sun’s Response to Interrogatory No. 6).

⁷ (Docket Entry No. 617, ¶ 1(d)).

⁸ (Ruiz Decl., Ex. 63, Vellturo Report, ¶ 155).

⁹ (Miller Decl., Ex. II, Vellturo Dep. Tr. (May 30, 2012) at 312:4-14) (“[T]here is a richer impact associated with that infringement that isn’t limited by that date in my analysis.”).

1366 (Fed. Cir. 2008) (“The correct measure of damages is a highly case-specific and fact-specific analysis.”).

In addition to the evidence presented, the Court takes note of the following, both of which were discussed in the Court’s December 20, 2012 Opinion: (a) Sun’s stipulation that its “importing into the United States of generic pantoprazole sodium tablets infringes claims 22 and 25 of U.S. Patent No. 4,758,579, if those claims are valid and enforceable,”¹⁰ and (b) Sun’s Response to Interrogatory No. 6, which provides that it first shipped its ANDA product to the United States on or around December 18, 2007. (SAF, ¶ 34; RSAF, ¶ 34) (Ruiz Decl., Ex. 71 at 7, Sun’s Response to Interrogatory No. 6); (SUMF, ¶ 23; RSUMF, ¶ 23).

Based on the foregoing, a finder of fact might reasonably conclude that Wyeth’s generic would never have been on the market in the absence of the infringement at issue in this case. Stated differently, a reasonable juror might find that lost sales of Protonix were reasonably foreseeable to Sun when it made the decision to import pantoprazole into the United States on or about December 18, 2007. *See, e.g., Rite-Hite*, 56 F.3d at 1546 (“If a particular injury was or should have been reasonably foreseeable by an infringing competitor in the relevant market, broadly defined, that injury is generally compensable absent a persuasive reason to the contrary.”). Because Wyeth’s generic was indisputably not on the market as of December 18, 2007, the Court finds, as a general matter, that Plaintiffs’ market reconstruction theory—if proven—is not deficient as a matter of law. *See Rite-Hite*, 56 F.3d at 1545 (“The question to be asked in determining damages is . . . had the Infringer not infringed, what would the Patentee Holder-Licensee have made?”) (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476 (1964)).

¹⁰ (SAF, ¶ 15; RSAF, ¶ 15; Docket Entry No. 617, ¶ 1(d)).

Sun relies, primarily, on the Federal Circuit's decisions in *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538 (Fed. Cir. 1995), and *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995), for the proposition that Plaintiffs are required, as a matter of law, to consider Wyeth's generic when conducting a lost sales analysis in this case. The Court has carefully reviewed both decisions and, for the following reasons, finds that (a) neither decision definitively includes such a requirement, and (b) the facts of this case are distinguishable from the circumstances at issue in those cases.

For instance, in *Rite-Hite*, the district court apportioned lost sales to two different products being sold by the patent holder in the relevant market—one that was covered by the patent-in-suit (MDL-55), and one that was not (ADL-100). In affirming, *inter alia*, the district court's award of lost sales pertaining to the ADL-100 product, the Federal Circuit concluded that Rite-Hite's lost sales of the ADL-100—a product that although not covered by the patent-in-suit, directly competed with the infringing product—were reasonably foreseeable. The facts of *Rite-Hite* are distinguishable inasmuch as there is no indication that the ADL-100 product was launched in response to or to mitigate the effects of the infringer's product. To the contrary, the ADL-100 product appears to have entered the market not only prior to the infringer's product, but even prior to the MDL-55 product (which was covered by the patent-in-suit).

The facts in *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211 (Fed. Cir. 1995) are equally distinguishable. In *Pall*, the owner of a patent for polyamide membranes used in microfiltration brought an infringement action against competitor MSI over a microfiltration membrane introduced by MSI which allegedly infringed the Pall patent. There, in remanding for a recalculation of damages, the Federal Circuit found that the existence of a competitor's product (the "Cuno product") constituted an acceptable noninfringing substitute for the Pall membranes

once Pall settled litigation and granted immunity to Cuno under the Pall patent. In particular, the Federal Circuit concluded that during the period before the Cuno products were licensed, they were not considered noninfringing substitutes, and thus, their presence in the market did not defeat Pall’s entitlement to lost profits damages for *all* of MSI’s infringing sales. However, the Court found that “after Pall settled with Cuno, the district court correctly held that Cuno’s presence in the marketplace could not be ignored, and limited the award of lost profits to the share of MSI’s sales that Pall would reasonably have made.” *Pall*, 66 F.3d at 1223. Here, on the other hand, Sun does not argue, for purposes of this motion, that Wyeth’s generic ever constituted an acceptable noninfringing substitute for purposes of the *Panduit* test. Moreover, the facts of the *Pall* case do not suggest that MSI’s infringement had any bearing on Pall’s decision to grant a license to the Cuno product.

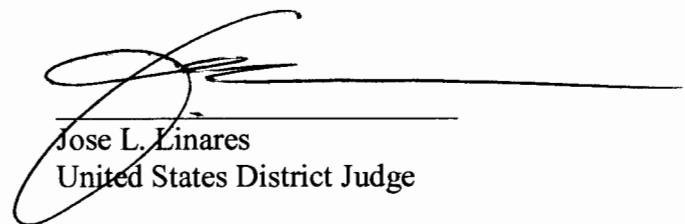
Simply put, neither case presents the unique fact pattern at issue in this case—namely, a patent holder’s attempt to exclude from the relevant “but for” infringement market a product, which—according to the patent holder—would never have been on the market in the absence of the patent infringement at issue. For all of the reasons discussed above, and absent a clearer directive from the Federal Circuit, the Court declines to find Plaintiffs’ hypothetical “but for” world deficient as a matter of law; rather, guided by logic and common sense, the Court finds that these are issues that should be presented to the jury. *See, e.g., Rite-Hite*, 56 F.3d at 1546 (“[T]he question of legal compensability is one ‘to be determined on the facts of each case upon mixed considerations of logic, common sense, justice, policy and precedent.’ ”); *Grain Processing*, 185 F.3d at 1350 (“[T]rial courts, with this court’s approval, consistently permit patentees to present market reconstruction theories showing all of the ways in which they would have been better off in the ‘but for world,’ and accordingly to recover lost profits in a wide

variety of forms."); *see generally Oiness v. Walgreen Co.*, 88 F.3d 1025, 1029 (Fed. Cir. 1996) ("The measurement of actual damages for patent infringement is a question of fact.").

CONCLUSION

For the reasons set forth above, Sun's motion for partial summary judgment [Docket Entry No. 1142] seeking a ruling that Plaintiffs are not entitled to lost profits against Sun for lost Protonix sales is **denied**. An appropriate Order accompanies this Opinion.

Date: January 11, 2013



Jose L. Linares
United States District Judge